

REMARKS

Claims 1-59 are now present in this application.

Claims 1, 8, 11-13, 15, 16, 26-28, 30 and 41-43 have been amended, and claims 51-59 have been presented. Reconsideration of the application, as amended, is respectfully requested.

It is noted that Information Disclosure Statements were submitted in the above-identified application on August 3, 2001 and September 28, 2001. While the Examiner has returned an initialed copy from the August 3, 2001 Information Disclosure Statement, such an initialed PTO-1449 form has not been returned for the September 28, 2001 Information Disclosure Statement. Notification of receipt of the September 28, 2001 Information Disclosure Statement, as well as consideration of all the documents cited therein, are respectfully requested.

Claims 1-50 stand rejected under 35 USC 112, first paragraph. This rejection is respectfully traversed.

The Examiner's attention is directed to page 17, points (1) and (2), wherein the second detection means for the gas flow is described. Also, on page 18 in points (3) and (4), the first detection means for the blood circulation is described. Hence, the ventilatory gases may be measured using an oxygen monitor, for example, and the arterial oxygen level may be measured using a pulse oxymeter or by invasive means.

With respect to claim 45, this claim uses the term "an apparently healthy individual." Accordingly, the risk of hypoxemia might not be recognized either by the individual or by the medical staff. In fact, a benefit of the present invention is that it allows for a fast screen of apparently healthy individuals that may be at risk of suffering from hypoxemia. Such individuals might not be identified in the absence of a fast screening procedure.

It is respectfully submitted that an enabling disclose is, in fact, provided. Reconsideration and withdrawal of the 35 USC 112, first paragraph rejection are respectfully requested.

Claims 1-50 also stand rejected under 35 USC 112, second paragraph. This rejection is respectfully traversed.

In view of the foregoing amendments, it is respectfully submitted that the claims should particularly point out and distinctly claim the subject matter of the instant invention. While Applicants do not agree that the original wording of the claims was indefinite, this change has been made merely to expedite prosecution. Withdrawal of the 35 USC 112, second paragraph rejection is respectfully requested.

Claims 15, 18-20, 22, 24-26, 28-30, 33, 34, 37-39, 41, 43, 44 and 46-48 stand rejected under 35 USC 103 as being unpatentable over SCHAFFER et al. This rejection is respectfully traversed.

The subject matter of claim 15 differs from SCHAFFER et al. by further including a step for determining whether additional measurements are required, including a determination of whether a steady state or equilibrium has been reached (note the description on pages 19-20). It is respectfully submitted that this independent claim 15 is inventive over SCHAFFER et al., as a skilled person would not be motivated by the teachings of SCHAFFER et al. to include such a step as a measured parameters of the invention of SCHAFFER et al. are determined continuously by the gas control system as noted in column 16, lines 55-64. The algorithm presented in Fig. 7 of the present invention establishing whether additional measurements are required (see step E and I for a specific interval of the at least two measurements) can be compared with the algorithm of SCHAFFER et al. in Fig. 12B. This algorithm of SCHAFFER et al. uses "actual values" of the ventilatory gases.

It is respectfully submitted that a person skilled in the art would not be motivated by SCHAFFER et al. to modify this arrangement to arrive at the invention as set forth in independent claim 15. The step of determining whether additional measurements are required represents one of the advantages of the present invention over the cited prior art. It enables a fast diagnostic result to be reached. Currently, the diagnostic results may be

obtained within 10-15 minutes by applying the present invention, as discussed on page 16, lines 22-25, for example.

Turning to claim 30, this arrangement differs from SCHAFFER et al. by further including a step for inserting the appropriate change in oxygen level in the inspired gas from the current oxygen level, so as to achieve a given desired target oxygen level in the blood. Thus, a prediction is made of a possible response of the patient to a change in the inspired gas for a fast diagnostic result to be reached with a minimal number of measurements. There is, however, no motivation or suggested in SCHAFFER et al. for one skilled in the art to adopt such a prediction scheme as the heliox ventilation conditions are monitored continuously and adjusted instantaneously using the feedback mechanism as described in column 17, lines 46-51. The expectation of success is also doubtful by using predictions instead of actual measurements as this would be hazardous to the patient. This is due to the fact that the heliox ventilation system requires high safety precautions as only a few breathing cycles with inappropriate respiratory parameters can be lethal to the patient. This is discussed in column 2, lines 15-29 of the patent.

In the embodiment of Figs. 8-10, for example, where the inspired oxygen fraction ($F_{I_{O_2}}$) in step E to F is adjusted by predictions of the most probable effect on the arterial oxygen

saturation (SpO₂/SaO₂), preferably within a 90% certainty interval. Such a scheme of forecasting diagnostic results would not be obvious to implant in the SCHAFFER et al. arrangement due to the high safety precautions described in this reference. It is respectfully submitted that claim 30 is not suggested or rendered obvious by the SCHAFFER et al. teaching.

Additionally, it is respectfully submitted that the remaining dependent claims should neither be suggested nor rendered obvious by this SCHAFFER et al. reference. Applicants gratefully acknowledge that the Examiner considers claims 1-14, 49 and 50 to contain allowable subject matter, if the 35 USC 112, first and second paragraph rejections were overcome. Because this has been done, these claims should be in condition for allowance. In addition, Applicants gratefully acknowledge that the Examiner considers claims 16-21, 23, 24, 27, 31, 32, 35, 36, 40 and 42 to contain allowable subject matter if the 35 USC 112, first and second paragraph rejections were overcome. These rejections should be overcome. Moreover, the claims from which these claims depend should also be in condition for allowance. All claims in the instant application should now be in condition for allowance. Accordingly, favorable reconsideration and an early Notice of Allowance are earnestly solicited.

Because the additional prior art cited by the Examiner has been included merely to show the state of the prior art and has not been utilized to reject the claims, no further comments concerning these documents are considered necessary at this time.

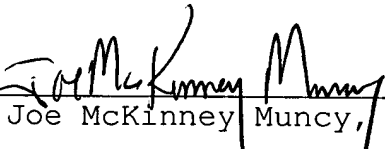
Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), the Applicants respectfully petition for a one (1) month extension of time for filing a response in connection with the present application and the required fee of \$55.00 is attached herewith.

In the event that any outstanding matters remain in this application, the Examiner is invited to contact the undersigned at (703) 205-8000 in the Washington, D.C. area.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 
Joe McKinney Muncy, #32,334

KM/asc
0459-0638P

P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000